DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 6 1989

Re: Nimotop
Docket No. 89E-0104

#16

The Honorable Donald J. Quigg
Assistant Secretary of Commerce
and Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Commissioner Quigg:

This is regard to the application for patent extension for U.S. Patent No. 4,406,906, filed by Bayer A.G., under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Nimotop, the human drug product claimed by the patent.

The total length of the review period for Nimotop is 3,403 days. Of this time, 1,108 days occurred during the testing phase and 2,295 days occurred during the approval phase. The periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: September 6, 1979.

   The applicant claims June 29, 1979 as the date the investigational new drug application (IND) for Nimotop became effective. However, FDA records indicate that the IND became effective on September 6, 1979.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: September 17, 1982.

   The applicant claims September 16, 1982 as the date the new drug application for Nimotop (NDA 19-869) was initially submitted. However, FDA records indicate that the application was not received until September 17, 1982.

3. The date the application was approved: December 28, 1988.

   FDA has verified the applicant's claim that NDA 19-869 was approved on December 28, 1988.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Louis E. Davidson
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